



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-
MAKING REVIEW COMMITTEE**

AGENCY: Health TITLE-SERIES: 64-43
RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No
RULE NAME: 64-43 Food Manufacturing Facilities

PRIMARY CONTACT

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CITE STATUTORY AUTHORITY: 16-1-4

EXPLANATION OF THE STATUTORY AUTHORITY FOR THE LEGISLATIVE RULE, INCLUDING A DETAILED SUMMARY OF THE EFFECT OF EACH PROVISION OF THE LEGISLATIVE RULE WITH CITATION TO THE SPECIFIC STATUTORY PROVISION WHICH EMPOWERS THE AGENCY TO ENACT SUCH RULE PROVISION:

The secretary may propose rules in accordance with the provisions of 29A-3-1 et seq. of this code that are necessary and proper to effectuate the purposes of this chapter.

IS THIS FILING SOLELY FOR THE SUNSET PROVISION REQUIREMENTS IN W. VA. CODE §29A-3-19(e)? No

IF YES, DO YOU CERTIFY THAT THE ONLY CHANGES TO THE RULE ARE THE FILING DATE, EFFECTIVE DATE AND AN EXTENSION OF THE SUNSET DATE? No

DATE eFiled FOR NOTICE OF HEARING OR PUBLIC COMMENT PERIOD: 6/30/2021

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED: 7/30/2021

COMMENTS RECEIVED: No

(IF YES, PLEASE UPLOAD IN THE COMMENTS RECEIVED FIELD COMMENTS RECEIVED AND RESPONSES TO COMMENTS)

PUBLIC HEARING: No

(IF YES, PLEASE UPLOAD IN THE PUBLIC HEARING FIELD PERSONS WHO APPEARED AT THE HEARING(S) AND TRANSCRIPTS)

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

WHAT OTHER NOTICE, INCLUDING ADVERTISING, DID YOU GIVE OF THE HEARING?

n/a

SUMMARY OF THE CONTENT OF THE LEGISLATIVE RULE, AND A DETAILED DESCRIPTION OF THE RULE'S PURPOSE AND ALL PROPOSED CHANGES TO THE RULE:

This legislative rule establishes the minimum requirements for the design, construction, management, and operation of food manufacturing facilities.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

Amendments reflect changes in federal regulations requiring food manufacturers selling products across state lines to comply with FDA regulations.

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED LEGISLATIVE RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

n/a

B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:

n/a

C. ECONOMIC IMPACT OF THE LEGISLATIVE RULE ON THE STATE OR ITS RESIDENTS:

n/a

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2021 Increase/Decrease (use "-")	2022 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost			0
Personal Services			0
Current Expenses			0
Repairs and Alterations			0
Assets			0
Other			0
2. Estimated Total Revenues			0

E. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

n/a

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

April L Robertson -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

TITLE 64
LEGISLATIVE RULE
BUREAU FOR PUBLIC HEALTH
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

SERIES 43
FOOD MANUFACTURING FACILITIES

§64-43-1. General.

1.1. Scope. -- This legislative rule establishes the minimum requirements for the design, construction, management, and operation of food manufacturing facilities.

1.2. Authority. -- W. Va. Code §16-1-4 and §16-7-1.

1.3. Filing Date. -- ~~April 4, 2019.~~

1.4. Effective Date. -- ~~July 1, 2019.~~

1.5. Sunset Provision. -- This rule shall terminate and have no further force or effect on ~~July 1, 2024~~upon August 1, 2027.

1.6. Applicability. -- This rule applies to the owners and operators of food manufacturing facilities engaged in wholesale operations. Food manufacturing facilities under the jurisdiction of the West Virginia Department of Agriculture are not subject to this rule. However, the provisions of this rule are inapplicable to cottage foods, acidified foods, non-potentially hazardous foods, and other exempted foods insofar as those foods and food products are regulated by the West Virginia Department of Agriculture by 64 CSR 38, promulgated pursuant to W. Va. Code §19-35-5.

1.7. Enforcement. -- This rule is enforced by the commissioner of the bureau for public health.

§64-43-2. Definitions.

2.1. Acidified foods. -- Low-acid foods to which acid(s) or acid food(s) are added. These foods include, but are not limited to, beans, cucumbers, cabbage, artichokes, cauliflower, puddings, peppers, tropical fruits, and fish, singly or in any combination. They have a water activity (aw) greater than 0.85 and have a finished equilibrium pH of 4.6 or below. These foods may be called, or may purport to be, "pickles" or "pickled." Carbonated beverages, jams, jellies, preserves, acid foods (including such foods as standardized and non-standardized food dressings and condiment sauces) that contain small amounts of low-acid food(s) and have a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food, foods that are stored, distributed, and retailed under refrigeration, and fermented are excluded.

2.2. Better process control school. -- A course recognized by the food and drug administration to meet the requirements of 21 CFR 113.10 and 21 CFR 114.10.

~~2.2.2.3.~~ Commissioner. -- Commissioner of the bureau for public health or his or her designee.

~~2.3.2.4.~~ Food Manufacturing Facility. -- Any person that manufactures, processes, or packs food for human consumption and conducts wholesale operations. This term does not include: farms, facilities regulated by legislative rule 64CSR17, "Food Establishments," and facilities under the regulatory authority of the West Virginia department of agriculture.

2.5. Juice. -- Aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions or one or more fruits or vegetables, or any concentrates of such liquid or puree.

~~2.4.2.6.~~ Low-acid foods. -- Any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity (aw) greater than 0.85. Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classed as low-acid foods.

~~2.5.2.7.~~ Permit. -- A document issued by the commissioner to operate a food manufacturing facility.

~~2.6.2.8.~~ Person. -- Individual, partnership, association, syndicate, company, firm, trust, corporation, government corporation, institution, department, division, bureau, agency, or any entity recognized by law.

2.9. Preventative controls qualified individual. -- An individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standard curriculum recognized as adequate by the food and drug administration or is otherwise qualified through job experience to develop and apply a food safety system.

~~2.7.2.10.~~ Processing Authority. -- A person who has been recognized by the association of food and drug officials as having expert knowledge of thermal processing requirements for low-acid foods packaged in hermetically-sealed containers or has expert knowledge in the acidification and processing of acidified foods and is found in the food processing authorities directory at: <https://www.afdo.org/directories/fpa/>.

2.11. Very small business. -- A business (including any subsidiaries and affiliates) averaging less than \$1,000,000 per year, adjusted for inflation, during the three year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale.

2.12. Wholesale. -- The sale or distribution of food to other business entities such as, but not limited to, retail stores, other food manufacturers, or food establishments.

§64-43-3. Incorporation by Reference of the Federal Code of Regulations.

3.1. The following portions of Title 21 ~~of the code of federal regulations, CFR Food and Drugs dated April 1, 2009,~~ are incorporated by reference:

~~3.1.a.3.1.1.~~ Chapter 1 Part 110 ~~Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food~~ 117 current good manufacturing practice, hazard analysis, and risk based preventive controls for human food with the following exceptions:

~~3.1.a.1. 110.80(b)(3)(i); and~~ 3.1.1.a. 21 CFR 117.5;

~~3.1.a.2. 110.80(b)(3)(iii);~~ 3.1.1.b. 21 CFR 117.7;

3.1.1.c. 21 CFR 117.8; and

3.1.1.d. 21 CFR 117, Subparts C and G shall not apply to facilities defined as a very small business, which shall comply with the requirements set forth in 21 CFR 117, Subpart D.

~~3.1.b.3.1.2. Chapter 1 Part 113 — Thermally Processed Low acid Foods Packaged in Hermetically Sealed Containers.~~ 21 CFR 113, thermally processed low acid foods packaged in hermetically sealed containers; and

~~3.1.c. Chapter 1 Part 114 — Acidified Foods.~~ 3.1.3. 21 CFR 114, acidified foods.

§64-43-4. General Requirements.

4.1. Whenever a food manufacturing facility is constructed or altered and whenever an existing structure is converted to a food manufacturing facility, plans and specifications for such construction, altering, or conversion shall be submitted to the commissioner for review and approval at least 45 days prior to the date the person intends to engage in business.

4.2. Facilities shall not begin manufacturing, processing, or packing food for human consumption until the facility has obtained or completed:

~~4.2.a.~~ 4.2.1. A permit to operate from the commissioner, as required in section 5 of this rule;

~~4.2.b.~~ 4.2.2. Label approval for all products from the West Virginia department of agriculture, and which complies with food labelling requirements of 21 CFR 101 for products sold in interstate commerce; and

~~4.2.c.~~ 4.2.3. Registration with the food and drug administration under the Public Health Security and Bio-Terrorism and Preparedness and Response Act of 2002. Exemptions shall be determined by the FDA.

4.3. Facilities ~~manufacturing Low acid Foods or Acidified Foods~~ shall also comply with requirements set forth in the code of federal regulations incorporated by reference in section 3 of this rule regarding ~~processing authority and proper school requirements,~~ better process control school, process control qualified individual training, and appropriate food safety training prior to manufacturing, processing, or packing food for human consumption.

4.4. All facilities governed by this rule shall maintain process records, have a written recall procedure, and flow charts of products. These documents shall be readily available to the commissioner.

4.5. If living or sleeping quarters are located on the premises, they shall be separated from rooms and areas used for food manufacturing facilities with complete partitioning and solid self-closing doors.

~~4.6. All facilities governed by this rule shall maintain refrigerated foods at 41 degrees Fahrenheit or below as appropriate for the particular food involved.~~

~~4.7. All facilities governed by this rule shall maintain hot foods at 135 degrees Fahrenheit or above.~~

§64-43-5. Permits.

5.1. No person shall operate a food manufacturing facility within the State of West Virginia who does not possess a valid permit issued by the commissioner.

5.2. An application for a permit to operate a food manufacturing facility shall be made in writing to the commissioner on a form prescribed by the commissioner.

5.3. A person shall apply for a permit at least 15 days before the date that the current permit expires or within ~~15~~45 days of the date before the actual or proposed operation of the facility is to be affected.

5.4. Permits shall not be transferable and shall become invalid upon a change of ownership.

5.5. A permit to operate expires at midnight on the 30th day of June following the date of issuance.

5.6. The commissioner may, without warning, notice, or hearing suspend a permit to operate a food manufacturing facility if the permit holder:

~~5.6.a.~~5.6.1. Does not comply with the requirements of this rule or if the operation of the food manufacturing facility constitutes an imminent public health hazard; or

~~5.6.b.~~5.6.2. The permit holder has been determined by the commissioner to have obstructed or hindered the commissioner in the proper discharge of his or her duties.

5.7. Operational permits shall be posted within the food manufacturing facility and be readily available to the commissioner.

§64-43-6. Inspections.

The commissioner shall conduct one or more preproduction inspections to verify that a food manufacturing facility is constructed and equipped in accordance with the plans and modifications as approved by the commissioner, and shall otherwise conduct as many inspections as necessary to assure compliance with this rule.

§64-43-7. Implementation.

7.1. Food manufacturing facilities in operation at the time this rule becomes effective, and meet Section 3 of this rule, are considered eligible for a permit to operate provided that any construction done after the effective date of this rule is in compliance with this rule.

7.2. New or extensively remodeled food manufacturing facilities whose plans and specifications received written approval from the commissioner prior to the effective date of this rule are eligible for a

permit to operate provided that the construction or remodeling is in compliance with the approved plans.

§64-43-8. Fees.

All facilities governed by this rule are subject to the appropriate fees established ~~in the Bureau for Public Health Legislative rule, Fees for Service, 64 CSR 51, Appendix B~~ by 64CSR51.

§64-43-9. Administrative Due Process.

Any person adversely affected by the enforcement of this rule desiring a contested case hearing to determine any rights, duties, interests, or privileges shall do so in the manner prescribed in ~~the West Virginia Department of Health's Procedural Rule, Rules of Procedure for Contested Case Hearings and Declaratory Rulings, 64CSR1.~~

§64-43-10. Penalty for Violating Provisions of Rule.

Any persons violating the provisions of this rule or orders pursuant to this rule is subject to the penalties provided in W. Va. Code §16-1-18 and §16-7-4.